

**REMARKS**

Claims 1-9 are pending in the application and under consideration in the Office Action mailed 27 May 2009. No claims are amended herein. Favorable reconsideration in light of the remarks which follow is respectfully requested.

Applicants respectfully submit that the presently pending claims fully distinguish the present invention over the prior art, and particularly over the references cited and relied upon in rejecting Applicants' claims in the Office action to which this Reply is responsive. Applicants respectfully request reconsideration and withdrawal of the rejections of the claims and notice of allowance of the present application.

**Rejections Over Castor**

Claims 1-9 stand rejected as anticipated by US 2002/130430 to Castor. Applicants respectfully traverse the rejections over Castor for at least the following reasons.

Applicants respectfully submit that Castor merely discloses a method of making polymeric spheres having an average diameter of between 0.01 and 10.0 microns by dissolving a polymeric material in a supercritical, critical, or near-critical fluid, and then "injecting" the resultant solution into a low solubility fluid. See, e.g., paragraphs 0038, 0041, 0044, 0046, and 0049 of Castor, in which the mixture is simply injected into a solution of PVA. Castor fails to describe that it is necessary to use an entrainer and such an entrainer is a solvent selected from low solubility fluids. Furthermore, as described in Examples 3 to 5 (in particular, paragraphs 0044, 0046, and 0049) of Castor, the polymer solution is "injected" into a low solubility fluid for 30 minutes. On the other hand, in the present invention, a polymer solution is "sprayed" into a poor solvent to cause rapid expansion. Therefore, the present invention is different from that of Castor, and is not anticipated thereby.

Applicants respectfully submit that there is a distinct difference between the "inject" of Castor and the "spray" of the present invention. In the method of Castor, the mixture of supercritical fluid, polymer and bioactive material is simply injected into, i.e., mixed with, the solution of PVA. There is no rapid expansion disclosed or suggested by Castor. While the Castor polymer and bioactive material form particles as a result of their insolubility in the solution of PVA, the mixture is not sprayed into the solution of PVA to cause rapid expansion. In contrast to the Castor injection mixing, the claims of the present application

clearly recite “spraying the resultant high pressure fluid into a poor solvent to cause rapid expansion”. Thus, the presently disclosed and claimed spraying causes rapid expansion and a much more efficient particle formation.

For these reasons, Applicants respectfully submit that claims 1-9 are not anticipated by Castor, and would not have been obvious thereover.

#### **Rejections over EP 711586**

Claims 1, 3-5 and 7-9 stand rejected as anticipated by EP 711586 (EP 586). Applicants respectfully traverse the rejections over EP 586 for at least the following reasons.

Applicants respectfully submit that EP 586 merely discloses a process for forming solid particulates by mixing the powder with the compressed liquid, and spraying the resultant mixture into a gaseous environment such as air. As described on the paragraph bridging columns 14 to 15 of EP 586, the environment into which the mixture is sprayed is a gaseous environment, and there is no suggestion for the use of a poor solvent in the both steps of mixing and spraying.

For these reasons, Applicants respectfully submit that claims 1, 3-5 and 7-9 are not anticipated by EP 586, and would not have been obvious thereover.

#### **Rejections over EP 711586 in view of Young et al.**

Claims 2 and 6 stand rejected as obvious over EP 711586 in view of Young et al. (“Rapid Expansion of Supercritical to Aqueous Solution to Produce Submicron Suspensions of Water-Insoluble Drugs”). Applicants respectfully traverse the rejection of these claims on this basis, for at least the following reasons.

Applicants respectfully submit that Young et al merely discloses that in order to obtain a dispersion of a drug, a supercritical solution in which a raw material is dissolved is rapidly expanded not into air but into water as a poor solvent. Since this method is aimed at obtaining a stable dispersion, it is necessary to add a surfactant such as Tween 80. As described above, since the purpose of Young et al is different from that of EP 0711586, those skilled in the art would not be motivated to combine Young et al and EP 0711586.

Applicants respectfully submit that the presently pending claims would not have been obvious over Kamasaka et al. in view of Masuhara et al. because neither reference, nor the asserted combination of references, teaches a composition as claimed. As such, Applicants submit that, even if these references are combined, it does not result in *prima facie* obviousness as not all the features of the claimed invention are taught by the asserted combination.

Accordingly, Applicants respectfully submit that none of the criteria necessary to establish a *prima facie* case of obviousness have been met, and as such, the outstanding obviousness rejections should be withdrawn.

In general, Applicants respectfully submit that none of Castor, EP 0711586 or Young et al disclose or suggest that the solution is sprayed into the poor solvent for rapid expansion to cause rapid supersaturation and precipitation. Therefore, the effect by using the poor solvent in the reduced pressure atmosphere would not have been expected by those skilled in the art.

Therefore, Applicants respectfully submit that the present invention is not anticipated by Castor and EP 0711586, and would not have been obvious over EP 0711586 and Young et al. Applicants respectfully request the Examiner to reconsider the rejection of the pending claims, to withdraw the rejection, and to indicate the allowability of the pending claims.

#### **Obviousness-type Double Patenting**

Applicants acknowledge the provisional rejection for obviousness type double patenting over co-pending U.S. Application No. 11/791578.

Claims 1-4 and 7-9 in the present application have been rejected over the co-pending application. Claims in the co-pending application have not yet been examined and so no patent has issued, and all grounds for rejection of the present application have not been withdrawn; accordingly the filing of a Terminal Disclaimer in the present application, to obviate an ODP rejection with respect to the co-pending application, is considered to be premature. When all of the remaining rejections of the claims of the present application have been overcome and the claims are allowed, an appropriate Terminal Disclaimer may be submitted, if warranted.

**Conclusion**

Applicants respectfully submit that the presently pending claims fully distinguish the present invention over the prior art, and particularly over the references cited and relied upon in rejecting Applicants' claims in the Office action to which this Reply is responsive. Applicants respectfully submit that the presently claimed invention is neither anticipated by, nor would have been obvious over, the cited references, either taken alone or in the asserted combination. Applicants respectfully request reconsideration and withdrawal of the rejections of the claims of the present application. For the foregoing reasons, Applicants respectfully submit that the claims are now in condition for allowance and request the examiner to indicate such.

In the event issues remain in the prosecution of this application, Applicants request that the Examiner telephone the undersigned to expedite allowance of the application. Should a further Extension of Time be necessary for a timely reply to the outstanding Office action, petition therefor is hereby made and, if any additional fees are required for the filing of this paper, the Commissioner is authorized to charge those fees to Deposit Account #18-0988, Docket No. NANJP0105US.

Respectfully submitted,

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